

Coronavirus Disease (COVID-19)

This document answers frequently asked questions about antibody or serology tests for SARS-CoV-2 which is the virus that causes COVID-19. It is important to note that this information will change and evolve so be sure to check resources such as the [FDA page](#) on testing for SARS-CoV-2 for frequent updates.

1. What is the difference between a serology test and a diagnostic test?

Serology tests do not diagnose active coronavirus infection. They are blood tests that check for proteins (antibodies) that develop in the body when the body responds to infection. On the other hand, diagnostic tests are molecular tests that mainly use a laboratory technique known as a polymerase chain reaction (PCR) that checks for genetic material from the virus itself. These tests can diagnose active infections through a sample usually from a nose or throat swab.

2. How long does it take an infected person to develop antibodies?

It typically takes one to two weeks after someone becomes sick with COVID-19 for their body to make antibodies, some people may take even longer. Depending on when someone was infected and the timing of the test, the serology test may not find antibodies in someone with a current COVID-19 infection.

3. Can a serology test be used to tell me if I have COVID-19 right now?

The serology test cannot determine if you currently have COVID-19; this test measures antibodies that indicate the body has responded to the virus without being able to note whether there is an active infection. In the early days of an infection when the body is still building its immune response antibodies may not be detected which can result in false negative serology test results. Similarly, positive serology tests may occur if the person had been infected with COVID-19 in the past and are not currently infected with the virus. Serology tests, therefore, shouldn't be used to diagnose COVID-19.

4. If serology tests shouldn't be used for diagnosis what are they used for?

These tests are used to gain a better understanding of how the immune response against the virus causing COVID-19 develops over time and how many people may have been infected or how far the pandemic has progressed. In the long run, serology testing and clinical follow-up may also help us to better understand whether a person who has recovered from infection is at lower risk of re-infection if they get exposed to the virus again. They can also help us to understand more about people who may have had the infection but never had symptoms since these individuals would also have developed antibodies.

5. Are these serology tests available now?

In March, the FDA issued a policy to allow developers of some serological tests to begin to market or use their tests once they have performed the appropriate evaluation to determine that their tests are accurate and reliable. This includes allowing developers to market their tests without prior FDA review if certain conditions outlined in the guidance document are met. Since this policy was issued many companies have come forward with tests.

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Serology test reports are required to state that negative results do not rule out COVID-19 infection and that follow-up testing with a diagnostic test should be considered to rule out infection. Test reports must also state that antibody tests should not be used to diagnose or exclude COVID-19 and that positive results could be due to past or present infection with other coronavirus strains. Companies that make these serological tests cannot make the claim that the FDA has validated the tests.

6. If I have a positive serology test can I stop wearing a cloth face covering or practicing social distancing?

Since we have no conclusive information that indicates that having antibodies to COVID-19 offers any immunity or prevents a person from becoming re-infected, persons with a positive antibody test result must continue to protect themselves and others from COVID-19. There is also the possibility of false positive serology test results, so it is required that everyone continue to adhere to the Safer at Home Health Officer order and continue to practice social distancing as well as other infection control practices such as wearing a cloth face covering in public, even if they have a positive serology test result.

7. Who should get the serological tests?

Serological tests should be done in consultation with your healthcare provider and with an understanding of the limitations around the test and the results. Your provider might choose to offer testing to help with larger efforts aimed at understanding the background rate of disease in the community. There are also research projects that are using serological tests to understand various aspects of the disease and these researchers will most likely continue to reach out to individuals to invite them to participate in their studies.

